

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Hargens, et al.

APPLICATION NO.: 10/566,188

FILED: June 15, 2007

FOR: TASTE-MASKED COMPOSITION OF CATIONIC EXCHANGE RESIN

EXAMINER: Valdez, Deve E.

GROUP ART UNIT: 1796

CONFIRMATION NO.: 2101

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Pre-Appeal Brief Request for Review

Sirs:

Applicants respectfully request pre-appeal brief review of the application.
Pending claims 1-8 stand finally rejected. A notice of appeal accompanies this paper.

Notice of Appeal

Applicants received a Final Office Action dated January 5, 2010 (the "Office Action") rejecting claims 1 and 2 as anticipated by EP 1175915 (hereinafter '915). The Office Action further rejects claims 3-8 as being unpatentable over '915 in view of WO 01/70194 which is equivalent to U.S. Patent No. 7,067,116 (hereinafter "BESS").

As Applicants explained in the Amendment dated September 18, 2009, (the "Amendment") the pending claims are directed to a process for producing a taste-masked composition. The process comprises the steps of loading a functionalized polymer matrix with an active compound to produce a loaded matrix and then subsequently washing the loaded matrix. (See Amendment at page 3, paragraphs 2 and 3). The washing step removes unbound active from the polymer matrix so that the unbound active will not impart a poor taste by releasing a substantial amount of the active in the mouth.

The Examiner has maintained anticipation and obviousness rejections citing '915. Reference '915 does not teach or suggest a washing step - - it only teaches using an active-containing matrix to load the active onto the matrix. (See Amendment at page 3, last two lines and page 4, first paragraph).

In paragraph 16 of the Office Action, the Examiner responded to the arguments Applicant made in the Amendment by citing paragraph [0054] of '915 and stating that "'915 teaches an acrylic anion exchange resin ...and addition of 6 grams of water ... added to the mixture." The Examiner notes this "vial was closed and the mixture was shaken." The Examiner concludes that "[t]he position is taken that the shaking step of ['915] is equivalent to the "washing step" of the instant invention."

The Examiner is in error. Paragraph [0054] of '915 states that the referred to solution also contains "indomethacin, a poorly soluble active substance." The step described in paragraph [0054] is a loading step, which could leave unbound indomethacin on the surface of the resin. No subsequent washing step is described after the indomethacin is infused into the resin, assisted by forming an aqueous solution and shaking. Applicants are uncertain why the Examiner is taking the position that the loading step described in paragraph [0054] is a washing step because it is not. No

subsequent rinse with a solution free of the active to dissociate unbound active from the resin is described or suggested.

The Examiner's stated reliance for BESS reference is not cure deficiencies in the absence of a washing step in '915.

In view of the above applicants respectfully request favorable reconsideration of the application.

Dated: 1/25/10

Respectfully Submitted,



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